

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT/OF COMMERCE U TRANSMITTAL LETTER TO THE UNITED STATES 286088US0PCT DESIGNATED/ELECTED OFFICE (DO/EO/US) U.S. APPLICATION NO. (If known, see 37 CFR 1.5) **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DA November 13, 2003 September 15, 2004 PCT/EP04/10300 TITLE OF INVENTION MULTILAYER DOSAGE FORM COMPRISING A MATRIX THAT INFLUENCES RELEASE OF A MODULATORY SUBSTANCE APPLICANT(S) FOR DO/EO/US Rosario LIZIO, et al. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). If the declaration is in a language other than the English language, it is accompanied by an English translation. The translation is accurate (37 CFR 1.69) An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). A copy of the International Preliminary Examination Report (PCT/IPEA/409). A copy of the International Search Report (PCT/ISA/210). Items 13 to 23 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 13. I b. Cited References c. Statement of Relevancy List of Related Cases. PTO-1449 An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). 22. A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4). 23. Other items or information: Notice of Priority/Request for Consideration/PCT/IB/304

IAP9 Rec'd PCT/PTO 22 MAR 2006

U.S. APPLICATION N	O Krown Sep 37 (F)	5) INTERNATIONAL PCT/EP04/	L APPLICATION NO.	286088US0PCT			
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24. Basic natio	onal fee	\$300.00					
25. Examination			v everination report				
prepared by IPEA	prepared by ISA/US or the US indicates all claims sa						
All other situations\$200				\$200.00			
26. Search fee							
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0							
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International Search F	Report prepared by an ISA						
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		\$400.00					
TOTAL OF	24, 25 AND 26 =			\$900.00			
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CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		<u> </u>		
Total claims	10 - 20 =	0	x \$50.00	\$0.00			
Independent claims	1 - 3=	0	x \$200.00	\$0.00			
MULTIPLE DEPENDE	ENT CLAIMS (if applicable	<del></del>	+ \$360.00	\$			
		TAL OF ABOVE C		\$900.00			
Applicant claims	s small entity status. See	37 CFR 1.27. Fees abo	ve are reduced by 1/2.  SUBTOTAL =				
		\$900.00					
	of <b>\$130.00</b> for furnishing t t claimed priority date (37	\$					
Hom the earnes	t claimed priority date (or	\$900.00					
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be				4000.00			
accompanied by	y an appropriate cover sh	\$					
Petition fee of \$	1,500.00 for Petition to R	\$					
TOTAL FEES ENCLOSED =				\$900.00 Amount to be			
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a A check in the amount of \$ to cover the above fees is enclosed.							
b. Please charge my Deposit Account No. <u>15-0030</u> in the amount of \$ to cover the above fees.							
c. The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account							
No. <u>15-0030</u> . A duplicate copy of this sheet is enclosed.							
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not							
be included on this form. Provide credit card information and authorization on PTO-2038.							
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.							
SEND ALL CORRESPONDCE TO:  CLISTOMED ALLIANDED							
CUSTOMER NUMBER SIGNATURE			Sundi	Sockas			
22850	SIGNATURE			olon a			
Tel. (703) 413-300			NAME	NAME Suringer Sachar			
Fax. (703) 413-22			24,618	Registration	No. 34,423		
(OSMMN 1/06)			REGISTRATION NU	MBER			

### IAP9 REC'DECTIPINO 22 MAR 2008

Docket No. 286088US0PCT

IN RE APPLICATION OF: Rosario LIZIO, et al.

SERIAL NO: New U.S. PCT Application Based on PCT/EP04/10300

FILED:

Herewith

FOR:

MULTILAYER DOSAGE FORM COMPRISING A MATRIX THAT INFLUENCES RELEASE OF A

MODULATORY SUBSTANCE

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

#### SIR:

Transmitted herewith is an amendment in the above-identified application.

- No additional fee is required
- ☐ Small entity status of this application under 37 C.F.R. §1.9 and §1.27 is claimed.
- Additional documents filed herewith: Credit Card Payment Form for \$900.00/PCT Transmittal Letter/Application Data Sheet/Notice of Priority/Preliminary Amendment/English Translation of Specification/

Declaration/PCT/IB/304/International Search Report/Request for Consideration

The Fee has been calculated as shown below:

CLAIMS	CLAIMS REMAINING		HIGHEST NUMBER PREVIOUSLY PAID	NO. EXTRA CLAIMS		RATE		CALCULATIONS
TOTAL	10	MINUS	20	0	х	\$50	=	\$0.00
INDEPENDENT	1	MINUS	3	0	х	\$200	=	\$0.00
	☐ MULTIPLE DEPENDENT CLAIMS			+	\$360	=	\$0.00	
		TOTAL OF ABOVE CALCULATIONS					\$0.00	
		☐ Reduction by 50% for filing by Small Entity					\$0.00	
						TOT	AL	\$0.00

□ Ac	heck in	the amount	of \$0.00	is attached
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- ☐ Credit card payment form is attached to cover the fees in the amount of **§0.00**
- Please charge any additional Fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.
- If these papers are not considered timely filed by the Patent and Trademark Office, then a petition is hereby made under 37 C.F.R. §1.136, and any additional fees required under 37 C.F.R. §1.136 for any necessary extension of time may be charged to Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Norman F. Oblon

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Customer Number

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Surinder Sachar

Registration No. 34,423

## IAPO REC'OPCTIFTO 22 MAR 2008

DOCKET NO.: 286088US0PCT

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Rosario LIZIO, et al. SERIAL NO.: NEW U.S. PCT APPLICATION

FILED: HEREWITH

INTERNATIONAL APPLICATION NO.: PCT/EP04/10300 INTERNATIONAL FILING DATE: September 15, 2004

FOR: MULTILAYER DOSAGE FORM COMPRISING A MATRIX THAT INFLUENCES

RELEASE OF A MODULATORY SUBSTANCE

# REQUEST FOR CONSIDERATION OF DOCUMENTS CITED IN INTERNATIONAL SEARCH REPORT

Commissioner for Patents Alexandria, Virginia 22313

Sir:

In the matter of the above-identified application for patent, notice is hereby given that applicant(s) request that the Examiner consider the documents cited in the International Search Report according to MPEP §609 and so indicate by a statement in the first Office Action that the information has been considered. When the Form PCT/DO/EO/903 indicates both the search report and copies of the documents are present in the national stage file, there is no requirement for the applicant(s) to submit them (1156 O.G. 91 November 23, 1993).

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C.

Customer Number 22850

(703) 413-3000 Fax No. (703) 413-2220 (OSMMN 08/03) Norman F. Oblon Attorney of Record Registration No. 24,618 Surinder Sachar

Registration No. 34,423